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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/600,145	06/19/2003	Sang-Yup Lee	HYLEE80.001C1	5042	
	7590 04/12/200		EXAMINER		
KNOBBE MARTENS OLSON & BEAR LLP  2040 MAIN STREET  MINNIFIELD, NITA M				D, NITA M	
FOURTEENTH FLOOR IRVINE, CA 92614			ART UNIT	PAPER NUMBER	
nevind, our sport			1645		
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE		
3 MO	NTHS	04/12/2007	ELECTRONIC		

## Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/12/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com eOAPilot@kmob.com

	Application No.	Applicant(s)	
	10/600,145	LEE ET AL.	
Office Action Summary	Examiner	Art Unit	
	N. M. Minnifield	1645	
The MAILING DATE of this communication a Period for Reply	ppears on the cover sheet w	ith the correspondence add	ress
A SHORTENED STATUTORY PERIOD FOR REF WHICHEVER IS LONGER, FROM THE MAILING  - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory perion.  - Failure to reply within the set or extended period for reply will, by stat Any reply received by the Office later than three months after the may earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNI 1.136(a). In no event, however, may a od will apply and will expire SIX (6) MOI ute, cause the application to become A	CATION.  reply be timely filed  NTHS from the mailing date of this com BANDONED (35 U.S.C. § 133).	
Status			
1) ☐ Responsive to communication(s) filed on <u>08</u> 2a) ☐ This action is <b>FINAL</b> . 2b) ☐ This action is <b>FINAL</b> . 2b) ☐ This action is application is in condition for allow closed in accordance with the practice under the practice under the practice.	nis action is non-final. vance except for formal mat		merits is
Disposition of Claims			
4) Claim(s) 1-31 is/are pending in the application 4a) Of the above claim(s) 27-31 is/are withdrest solutions. Claim(s) 1-6,8-13,15-22 and 24-26 is/are allowed by the claim(s) 7,14 and 23 is/are rejected.  7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and claim(s) are subject to restriction and claim(s). The specification is objected to by the Examination of the drawing(s) filled on is/are: a) are subject and objection to the correct solutions.	awn from consideration.  owed.  I/or election requirement.  ner.  ccepted or b)  objected to  ne drawing(s) be held in abeya	nce. See 37 CFR 1.85(a).	R 1 121(d)
11) The oath or declaration is objected to by the	•	• •	· ·
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the prapplication from the International Bure * See the attached detailed Office action for a li	ents have been received.  Ints have been received in A  Iority documents have beer  Iority (PCT Rule 17.2(a)).	Application No  received in this National S	tage
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	Paper No(	Summary (PTO-413) s)/Mail Date. <u>attached</u> . nformal Patent Application 	

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## **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 8, 2007 has been entered.

## Sequence Requirements

2. This application contains sequence disclosures, see [0041] and [0020], that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2).

Full compliance with the sequence rules is required in response to this office action. A complete response to this office action should include both compliance with the sequence rules and a response to the non-final office action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

3. Applicants' amendment filed January 8, 2007 is acknowledged and has been entered. Claims 1, 7, 12, 15, 17, 19, 22, 25 and 26 have been amended. Claims 1-31 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments, with the exception of those discussed below.

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4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

- 5. Claims 27-31 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 8, 2007.
- 6. Claims 1-26 is being examined in this application.
- 7. Claims 7, 14 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is vague and indefinite in the recitation of "an amino acid sequence comprising the sequence for  $\beta$ -endorphin".  $\beta$ -endorphin is a 31 amino acid protein; it is not clear which portion of the 31 amino acids of  $\beta$ -endorphin protein is encompassed by the recitation of "an amino acid sequence comprising the sequence for  $\beta$ -endorphin". The specification states that "[A]s shown in Table 1 above, 2.8mg of  $\beta$ -endorphin was purified by the technique of HPLC. Further, N-terminal sequencing of purified  $\beta$ -endorphin revealed that the amino acid sequence is Tyr-Gly-Gly-Phe-Met-Thr-Ser-Glu-Lys, which corresponds with N-terminal amino acids of  $\beta$ -endorphin. [0041] Does Applicant intend these 9 amino acids of the amino terminal that were sequenced from the secreted fusion protein to be "an amino acid sequence comprising the sequence for  $\beta$ -endorphin"?

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Applicants should consider amending the claims to a specific SEQ ID NO that sets forth the amino acid sequence comprising the sequence for  $\beta$ -endorphin.

Claim 14 is vague and indefinite in the recitation of "wherein said microorganism comprises *E. coli…*". Does Applicant intend that there is more than one microorganism present? Is there more than *E. coli* present?

Claim 23 lacks positive antecedent basis in the recitation of "OmpF fusion protein and in the recitation of "media". There is insufficient antecedent basis for these limitations in the claim.

- 8. Claims 1-6, 8-13, 15-22 and 24-26 are in condition for allowance.
- 9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
- 10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Primary Examiner
Art Unit 1645

**NMM** 

April 2, 2007